

# **3M DURAPREP SURGICAL- iodine povacrylex and isopropyl alcohol solution**

## **3M Company**

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### **Drug Facts**

#### **Active ingredients**

Iodine povacrylex (0.7% available iodine)

Isopropyl alcohol, 74% w/w

#### **Purpose**

Antiseptic

Antiseptic

#### **Uses**

##### **patient preoperative skin preparation:**

- for preparation of the skin prior to surgery
- helps reduce bacteria that potentially can cause skin infection

#### **Warnings**

**For external use only. Flammable, keep away from fire or flame.**

##### **To reduce the risk of fire, PREP CAREFULLY:**

- solution contains alcohol and gives off flammable vapors
- do not drape or use ignition source (e.g., cautery, laser) until solution is completely dry (minimum of 3 minutes on hairless skin; up to 1 hour in hair).
- avoid getting solution into hairy areas. **Wet hair is flammable.** Hair may take up to 1 hour to dry.
- do not allow solution to pool
- remove solution-stained material from prep area



#### **Do not use**

- on patients with known allergies to iodine or any other ingredients in this product
- on open wounds, on mucous membranes, or as a general skin cleanser
- in infants less than 2 months old due to the risk of excessive skin irritation and transient hypothyroidism

#### **When using this product**

- keep out of eyes, ears, and mouth. May cause serious injury if permitted to enter and

remain. If contact occurs, flush with cold water right away and contact a doctor.

- to avoid skin injury, care should be taken when removing drapes, tapes, etc...applied over film
- use with caution in women who are breast-feeding due to the potential for transient hypothyroidism in the nursing newborn

**Stop use and ask a doctor if** irritation, sensitization or allergic reaction occurs. These may be signs of a serious condition. On rare occasions, use of this product has been associated with skin blistering.

**Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center right away.

### **Directions (follow all directions for use)**

- at the end of the prep, discard any portion of the solution which is not required to cover the prep area. It is not necessary to use the entire amount available.

### **Getting Patient Ready for Solution:**

- use in well-ventilated area
- do not microwave or heat the solution applicator
- apply to clean, completely dry, residue-free, intact skin
- when hair removal is necessary, use a surgical clipper on the morning of the surgery. If a wet shave is used, thoroughly remove all soap residues.

### **Activating the Applicator:**

- grasp product by wrapping hand and fingers around the labeled portion of the applicator. Place thumb on the lever.
- with sponge face parallel to the floor, snap lever. Allow all fluid to flow into sponge.

### **When Applying Solution:**

- **DO NOT SCRUB.** Paint a single, uniform application and do not reprep area.
- **do not allow solution to pool.** Use sponge applicator to absorb excess solution and continue to apply a uniform coating. If solution accidentally gets outside of prep area, remove excess with gauze.
- tuck prep towels as needed under both sides of the neck to absorb excess solution. Remove towels before draping.
- avoid getting solution into hairy areas. **Wet hair is flammable.** Hair may take up to 1 hour to dry.
- when prepping skin folds, toes, or fingers, use a sterile-gloved hand to hold skin apart until completely dry. Otherwise, skin may adhere to itself.



### **After Applying Solution:**

- to reduce the risk of fire, **wait until solution is completely dry (minimum of 3 minutes on hairless skin; up to 1 hour in hair).** Solution will turn from a shiny to a dull appearance on skin alerting the user that the solution is completely dry and no longer flammable.

**While Waiting for Solution to Completely Dry:**

- do not drape or use ignition source (e.g., cautery, laser)
- check for pooled solution. Use sterile gauze to soak up pooled solution. Do not blot because it may remove solution from skin.
- remove solution-stained materials. Replace if necessary.

**After Solution is Completely Dry:**

- to reduce the risk of fire, begin draping and/or using cautery only after solution is completely dry and all solution-stained materials are removed
- if incise drapes are used, apply directly to dry prep. On completion of surgical procedure, removal of incise drape will remove film.
- apply dressing following standard practices

**Other information**

- store between 20-25°C (68-77°F)
- avoid excessive heat above 40°C (104°F)
- solution is not water soluble and may stain. Therefore, avoid contact with reusable items (basins, instruments).

**Inactive ingredients**

ethyl alcohol, water

**Questions?**

call 1-800-228-3957 (Monday to Friday 7AM – 6PM CST). [www.3M.com](http://www.3M.com).

**Principal Display Panel - 6 mL Applicator Label**

**3M**

STERILE EO

NDC 17518-011-07

**Do Not Reuse**

**1. SNAP**

**2. PAINT, DO**

**NOT SCRUB**

**DuraPrep™**

**Surgical Solution**

**Iodine Povacrylex** (0.7% Available Iodine) and **Isopropyl Alcohol** (74% w/w)

## Do Not Reuse

**Latex-Free**

**Not Made With Natural Latex**

Single Use

DuraPrep Surgical Solution is a film-forming iodophor complex. Each unit dose applicator contains 0.2 fl oz (6 mL) of solution which covers an approximate 8 in x 10 in area.

3M recommends all users participate in product in-service training prior to use. In-servicing is available on video, from your 3M sales representative, or at the 3M website ([www.3M.com](http://www.3M.com)).

**REF 8635 0.2 fl oz • 6 mL**

**3M**

Made in U.S.A. by



**3M Health Care**

2510 Conway Ave

St. Paul, MN 55144

1-800-228-3957

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**3M****DuraPrep™**  
Surgical Solution

Iodine Povacrylex  
(0.7% Available Iodine)  
and Isopropyl Alcohol (74% w/w)  
Patient Preoperative Skin Preparation  
Non-sterile Solution

Applicator is sterile if package is intact  
For head, neck, and small prep areas

STERILE EO

NDC 17518-011-07  
MAL09032040XRNot Made With  
Natural Rubber LatexDo Not  
Reuse**WARNING**  
**Flammable**

Keep away from fire or flame.

To reduce the risk of fire, PREP CAREFULLY:

- Solution contains alcohol and gives off **flammable vapors**.
- Do not drape or use ignition source (e.g., cautery, laser) until solution is completely dry (minimum of 3 minutes on hairless skin; up to 1 hour in hair).
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(01) 0 03 17518 01107 8

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**Patient Take Home Instructions**

Your surgeon used 3M™ DuraPrep™ Surgical Solution 8635, a bacteria-killing skin preparation. It is recommended that this film remain on the skin after the procedure. The film will gradually wear away. If, however, early removal is desired:

- Apply 8610 or 8611 3M™ Remover Lotion to the prepped area keeping away from the wound edge or puncture site. Wipe off with a disposable towel, or
- Soak gauze with 70% isopropyl alcohol and place on the prepped area for at least 40 seconds. Lightly scrub to remove the solution.

If you have questions, call 1-800-228-3957

**3M DURAPREP SURGICAL**

iodine povacrylex and isopropyl alcohol solution

**Product Information****Product Type**

HUMAN OTC DRUG

**Item Code (Source)**

NDC:17518-011

**Route of Administration**

TOPICAL

**Active Ingredient/Active Moiety**

Ingredient Name		Basis of Strength	Strength	
Iodine Povacrylex (UNII: 6E43AWY083) (Iodine - UNII:9679TC07X4)		Iodine	6.02 mg in 1 mL	
Isopropyl Alcohol (UNII: ND2M416302) (Isopropyl Alcohol - UNII:ND2M416302)		Isopropyl Alcohol	636.4 mg in 1 mL	
Inactive Ingredients				
Ingredient Name		Strength		
Alcohol (UNII: 3K9958V90M)				
Water (UNII: 059QF0KO0R)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:17518-011-07	1 in 1 CASE	09/29/2006	
1		6 mL in 1 APPLICATOR; Type 0: Not a Combination Product		
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA		NDA021586	09/29/2006	

**Labeler** - 3M Company (006173082)

## Establishment

Name	Address	ID/FEI	Business Operations
3M Company		054950670	ANALYSIS(17518-011) , PACK(17518-011)

## Establishment

Name	Address	ID/FEI	Business Operations
3M Company		078671244	MANUFACTURE(17518-011)

## Establishment

Name	Address	ID/FEI	Business Operations
3M Company		830016148	ANALYSIS(17518-011)